

REMARKS

The limitation of claim 8 has been incorporated into claim 1. Claim 8 has accordingly been canceled. Claims 9 and 10 have been amended to correct dependency. Claim 11 has been amended to depend on new claim 22. Support may be found e.g., in the paragraph bridging pages 12 and 13. No new matter has been added. Entry is requested.

Applicants' claimed invention is directed to an adhesive comprising an acrylic polymer. The acrylic polymer is characterized as being prepared from monomers selected from the group consisting of alkyl acrylate monomers, alkyl methacrylate monomers and polymerizable non-cyclic nitrogen-containing monomers. The alkyl acrylate monomer and alkyl methacrylate monomers used to prepare the polymer are further characterized as having up to about 18 carbon atoms in the alkyl group. The acrylic polymer required for use comprises, on a dry weight basis of the total monomer weight of the polymer, from about 50 to about 98% of the alkyl acrylate monomers and/or alkyl methacrylate monomers and from about 2 to about 50% of the polymerizable non-cyclic nitrogen-containing monomers, lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker.

The examiner sets forth 8 grounds of rejection.

- (1) Claims 1-7 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 3,491,070 (Weaver).

The examiner (office action, paragraph 3) interprets the claims as requiring polymer prepared from monomers selected from the group consisting of alkyl acrylate monomer, alkyl methacrylate monomer and polymerizable non-cyclic monomer, and as further requiring 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers.

Weaver is cited by the examiner as disclosing an adhesive obtained by the combination of monomers to form polymers consisting of 80-96% of 2-ethylhexyl acrylate and 2.0-19% octyl acrylamide to create a polymer combination that is synergistic in nature. The examiner refers to col. 1, lines 52-60. The examiner further urges that the

Tg of applicants' claim 4 is inherent for the specific polymer.

Applicants disagree with the examiner's characterization of the claimed invention. Applicants further disagree that the claimed invention is anticipated by Weaver.

The cited Weaver patent discloses adhesive compositions that comprise a polymer composition based on an acrylate monomer and two specific acrylamide monomers (i) N-octyl acrylamide and (ii) methylacrylamide. As disclosed at col.1, lines 52-60, Weavers invention is based on the discovery that a specific combination of two particular acrylamides with 2-ethylhexyl acrylate creates a combination that is synergistic in nature, and that all three monomers must be present in the adhesive composition. The ranges disclosed as being preferred are 80-96 by wt. 2-ethylhexyl acrylate, 2.0-19 by wt. N-octyl acrylamine and 1-4 by wt. methylacrylamide.

The examiner has clearly mischaracterized the teaching of Weaver by omitting the required and essential methylacrylamide monomer component of Weaver. The examiner has also failed to characterize the acrylic polymer required for use in the practice of applicants' invention as one lacking functional groups containing reactive hydrogen. In addition, there is no disclosure in Weaver of an adhesive that contains a therapeutic agent as required in the practice of applicants' invention. The polymer of Weaver does not contain each of the required limitations of applicants' claimed invention and, as such, fails to anticipate claims 1-7.

Claims 1-7 are not anticipated by Weaver. Reconsideration and withdrawal of this Section 102 rejection is requested.

(2) Claims 1-7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Delgada (U.S. Patent 4,988,567).

The examiner (office action, paragraph 4) again interprets claim 1 as requiring polymer prepared from monomers selected from the group consisting of alkyl acrylate monomer, alkyl methacrylate monomer and polymerizable non-cyclic monomer, and as further requiring 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers.

Delgada is cited by the examiner as disclosing a polymer formed of at least 70 % alkyl acrylate such as 2-ethylhexyl acrylate and up to 30 % of octyl acrylamide. The examiner refers to col. 5, lines 19-55. The examiner further urges that the Tg of applicants' claim 4 is inherent for the specific polymer.

Applicants again disagree with the examiner's characterization of the claimed invention. Applicants further disagree that the claimed invention is anticipated by Delgada.

Delgada discloses pressure sensitive adhesives that consist essentially of acid-free hollow microspheres that comprise alkyl acrylate or alkyl methacrylate ester and one or more nitrogen containing polar monomers. The microspheres are prepared by forming a water-in-oil emulsion comprising an aqueous solution of a nitrogen containing polar monomer in an oil phase containing alkyl acrylate and/or alkyl methacrylates, and thereafter initiating polymerization.

Delgada fails to disclose an adhesive comprising acrylic polymer, which polymer is prepared from monomers selected from the group consisting of alkyl acrylate monomers, alkyl methacrylate monomers and polymerizable non-cyclic nitrogen-containing monomers, lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker, and wherein the adhesive also comprises a therapeutic agent.

Claims 1-7 are not anticipated by Delgada. Reconsideration and withdrawal of this Section 102 rejection is requested.

(3) Claims 1-7, 18 and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ramharack et al. (U.S. Patent 5,391,406).

The examiner (office action, paragraph 5) again interprets claim 1 as requiring polymer prepared from monomers selected from the group consisting of alkyl acrylate monomer, alkyl methacrylate monomer and polymerizable non-cyclic monomer, and as further requiring 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers.

Ramharack is cited by the examiner as disclosing a polymer made by polymerizing 80 % 2-ethylhexyl acrylate and up to 20 % vinyl monomer including t-octyl acrylamide, and as having a Tg in the range of -60°C to +5°C. The examiner refers to col. 2, lines 47-50 and 64-68 and col. 3, lines 3-10 and 42-60). The examiner further urges that the acrylate monomer may further contain other acrylate monomers such as methyl acrylate. The examiner refers to col. 3, lines 61-68; col. 6, lines 46-52; col. 11, lines 25-40 and col. 12, lines 22-27.

Applicants again disagree with the examiner's characterization of the claimed invention. Applicants further disagree that the claimed invention is anticipated by Ramharack.

Applicants' claimed invention is directed to an adhesive comprising an acrylic polymer. While the polymers are prepared from monomers selected from the group consisting of alkyl acrylate monomers, alkyl methacrylate monomers and polymerizable non-cyclic nitrogen-containing monomers, and comprise from about 50 to about 98% of the alkyl acrylate monomers and/or alkyl methacrylate monomers, the alkyl acrylate monomers and alkyl methacrylate monomers used to prepare the polymer are further characterized as having up to about 18 carbon atoms in the alkyl group. The acrylic polymer, in addition to comprising from 50 to about 98% of the alkyl acrylate monomers and/or alkyl methacrylate monomers, also comprises from about and from about 2 to about 50% of the polymerizable non-cyclic nitrogen-containing monomers, lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker.

Ramharack discloses UV curable hot melt adhesives. The adhesive is prepared by copolymerizing acrylic monomers, or a combination of acrylic and vinyl monomers, with the functional monomer m-TMI to give a saturated polymer with pendent vinyl groups that are crosslinked by UV radiation. Included must be at least one acrylic or vinyl monomer that also contains a functional group and at least one acrylic or vinyl monomer that also contains photoinitiator functionality. The saturated polymeric chain has both pendant unsaturation and pendant photoinitiator. The resulting solid is heated, coated onto a substrate, and then exposed to UV radiation to crosslink the pendent vinyl groups.

The adhesive of Ramharack does not comprise and adhesive that comprising an acrylic polymer prepared from monomers selected from the group consisting of alkyl acrylate monomers, alkyl methacrylate monomers and polymerizable non-cyclic nitrogen-containing that lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker. Moreover, the adhesive fails to disclose an adhesive that also comprises a therapeutic agent so as to anticipate applicants' claimed invention.

Claims 1-7, 18 and 19 are not anticipated by Ramharack. Reconsideration and withdrawal of this Section 102 rejection is requested.

(4) Claims 1-6, 8-17 and 21 are rejected under 35 U.S.C. § 102 (b) as being anticipated by WO 96/08229.

The examiner (office action, paragraph 6) interprets claims 1 and 12 as requiring polymer prepared from monomers selected from the group consisting of alkyl acrylate monomer, alkyl methacrylate monomer and polymerizable non-cyclic monomer, and as further requiring 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers.

The examiner cites WO 96/08229 as disclosing pressure sensitive adhesive compositions comprising an acrylic polymer comprising 40-95 % of one or more A monomers selected from alkyl acrylates and alkyl methacrylates having 4-10 carbon atoms and up to 60% of one or more B monomers which include monomers that are polymerizable non-cyclic nitrogen containing monomer. While tacitly acknowledging that the polymer also comprises a macromonomer, the examiner concludes that the macromonomer is an alkyl methacrylate . The examiner further notes that the polymer composition of WO 96/08229 is used to form matrices for transdermal drug delivery devices, which devices comprise a backing layer, a matrix layer comprising the composition and a therapeutic agent and a release liner, that WO 96/08229 contemplates various drugs for delivery by the device, including analgesics such as fentanyl. The examiner further cites WO 96/08229 as teaching pressure sensitive adhesives having a Tg of -10°C.

Applicants again disagree with the examiner's characterization of the claimed

invention. Applicants further disagree that the claimed invention is anticipated by WO 96/08229.

While the examiner has failed to characterize the acrylic polymer required for use in the practice of applicants' invention as one in which the alkyl (meth)acrylate monomers used to prepare the polymer contain less than 18 carbon atoms, the examiner urges that the polymer of WO 96/08229 meet the required claim limitations.

Applicants have previously argued that the copolymer disclosed in WO 96/08229 comprises one or more A monomers, one or more optional B polymer and a macromonomer that is a required and necessary component of the disclosed copolymer. It was further argued that the alkyl acrylate and alkyl methacrylate monomers required for use in the practice of the claimed invention can only have up to about 18 carbon atoms in the alkyl group and, as such, are not considered in the art to be macromonomers, as this term is conventionally used in the art and used in the disclosure of the WO 96/08229 patent. The examiner continues to maintain the position that both the A monomers and the macromonomers of WO 96/08229 read on applicants' alkyl acrylate and/or alkyl methacrylate monomers. In support of this position, the examiner points to the disclosure on page 8, lines 15-19 of WO 96/08229. The examiner characterizes this disclosure as giving "examples of macromonomers as those disclosed by US 4,732,808." The examiner, referring to col. 5, lines 28-33 of the '808 patent, states that "by careful review of that patent it became apparent that such macromonomers contain 4-12 carbon atoms." The examiner concludes that the since applicants' claims do not require both alkyl acrylate monomers and alkyl methacrylate monomers that the claimed invention is anticipated by WO 96/08229.

Applicants agree with the examiner's interpretation of the claims as not requiring both alkyl acrylate and alkyl methacrylate monomers. Applicants, however, strongly disagree with the examiner's position that WO 96/08229 disclose a polymer comprising monomer A, monomer B and, as macromonomer, an alkyl methacrylate, and submits that the examiner has grossly distorted the teachings WO 96/08229 as well as the '808 patent.

WO 96/08229, page 8, lines 15-18, discloses "[s]uch macromonomers are known and

may be prepared by the method disclosed in U.S. Pat. Nos. 3,786,116, 3,842,059 (both to Milkovich et al.) and 4,732,808 (Krampe et al.)". The examiner not only takes this sentence out of context of the paragraph from which it was excised, but then proceeds to mischaracterize the teaching of the '808 patent by pointing to the described monomer A components of the '808 (col.5, lines 28-33) as examples of the macromonomers of WO 96/08229. In fact, the '808 patent discloses an adhesive comprising a copolymer of copolymerized A monomers, C macromers and optional B monomers. The A monomers of the '808 patent are not examples of the macromonomers required for use in preparing the polymer of WO 96/08229.

Applicants' claims 1-6, 8-17 and 21 are not anticipated by the disclosure of the WO 96/08229 patent. There is no teaching in the WO 96/08229 disclosure that the macromonomers are not required and, as such, WO 96/08229 fails to render the invention of claims 7 and 18-20 obvious to one of ordinary skill in the art. Reconsideration and withdrawal of this Section 102 rejection is requested.

5. Claims 1-11 and 14 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,077,527 (Tan et al.).

The examiner (office action, paragraph 8) interprets claims as requiring polymer prepared from monomers selected from the group consisting of alkyl acrylate monomer, alkyl methacrylate monomer and polymerizable non-cyclic monomer, and as further requiring 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers.

Tan is cited by the examiner as disclosing a pressure sensitive composition for use in transdermal drug delivery devices comprising at least 40 % by weight of alkyl acrylate including n-butyl acrylate and 2-ethylhexyl acrylate and 10-60% by weight of substituted acrylamide or methacrylamide including t-octyl acrylamide. The examiner refers to the abstract; col. 2, lines 45-60; col.3, lines 60-67; col.4, lines 8-16. The examiner further calculates the T_g of the composition to be below 10°C. Finally, the examiner urges that the reference does not disclose any reactive groups after crosslinking.

Applicants disagree. Applicants again submit that the claimed invention is patentable over the Tan patent. The Tan patent does not disclose *any* acrylic polymer that lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker as required in the practice of the claimed invention. Moreover, the Tan patent does not disclose *any* acrylic polymer that contains only alkyl (meth) acrylate monomers and polymerizable non-cyclic nitrogen-containing monomers. All exemplified embodiments of the Tan patent (Examples 1-7 and Comparative Example 8) use vinyl acetate and use acrylic acid as a functional monomer (i.e., a reactive species). There is no specific disclosure of an acrylic polymer prepared only from alkyl (meth) acrylate monomers and polymerizable non-cyclic nitrogen-containing monomers, which polymer does not contain functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker so to anticipate the claimed invention.

In response to applicants' argument that Tan does not disclose any acrylic polymer prepared only from alkyl (meth) acrylate monomers and polymerizable non-cyclic nitrogen-containing monomers the examiner (Office action, paragraph 9) refers to the claim language as requiring polymer prepared from monomers selected from the group consisting of alkyl acrylate, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen containing monomers. The examiner concludes that the claims can be a polymer of any one of these three monomers. The examiner further urges that the claims recite polymer comprising 50-98% of alkyl acrylate monomers and/or alkyl methacrylate monomers. The examiner urges that the claim language does not exclude other polymers.

Applicants claimed adhesive does not exclude other polymers, but must include a polymer prepared from monomers selected from the group consisting of the (meth) acrylate monomers and polymerizable non-cyclic nitrogen-containing monomers, and comprising, on a dry weight basis of the total monomer weight of the polymer, from about 50 to about 98% of alkyl acrylate monomer and/or alkyl methacrylate monomer and from about 2 to about 50% of polymerizable non-cyclic nitrogen-containing monomers. Thus the claims

cannot be read to contain just any one of the recited alkyl acrylate, alkyl methacrylate or polymerizable non-cyclic nitrogen-containing polymer as urged by the examiner.

Again, the examiner's interpretation of applicants' claims as requiring polymer prepared from monomers selected from the group consisting of alkyl acrylate monomer, alkyl methacrylate monomer and polymerizable non-cyclic monomer, and as further requiring 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers is incomplete.

Applicants' claimed adhesive must contain a polymer prepared from monomers selected from the group consisting of alkyl acrylate monomers, alkyl methacrylate monomers and polymerizable non-cyclic nitrogen-containing monomers. The alkyl acrylate monomer and alkyl methacrylate monomers used to prepare the polymer are further characterized as having up to about 18 carbon atoms in the alkyl group. The acrylic polymer required for use comprises, on a dry weight basis of the total monomer weight of the polymer, from about 50 to about 98% of the alkyl acrylate monomers and/or alkyl methacrylate monomers and from about 2 to about 50% of the polymerizable non-cyclic nitrogen-containing monomers, lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker.

Applicants' adhesive is not disclosed by Tan so as to anticipate the claimed invention. Again, all exemplified embodiments of the Tan patent (Examples 1-7 and Comparative Example 8) use vinyl acetate and use acrylic acid as a functional monomer (i.e., a reactive species). The Tan patent does not disclose *any* acrylic polymer prepared only from alkyl (meth) acrylate monomers and polymerizable non-cyclic nitrogen-containing monomers and which lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker as required in the practice of the claimed invention.

While armed with applicants' disclosure, the skilled practitioner could pick and choose various components of Tan which could be used to prepare a polymer disclosed for use in applicants' adhesive, such a polymer is not specifically disclosed. As such, Tan fails to anticipate the claimed invention.

Claims 1-11 and 14 are not anticipated by Tan. Reconsideration and withdrawal of this Section 102 rejection is requested.

6. Claim 7 is rejected under 35 U.S.C. § 103 (a) as being obvious over WO 96/08229 in view of Weaver (U.S. Patent No. 3,491,070).

The examiner (office action, paragraph 12) acknowledges that WO 96/08229 fails to teach specific octyl acrylamide required for use in claim 7. The examiner urges that Weaver teaches the use of t-octyl combined with 2-ethylhexyl acrylate has good tack and creates a polymer combination that is synergistic in nature. It is the examiner's position that it would have been obvious to deliver polymer adhesive composition made of alkyl acrylate monomer and acrylamide monomer as disclosed by WO 96/08229, and replace the acrylamide monomer with t-octyl acrylamide disclosed in Weaver, motivated by the teaching of Weaver that the combination of alkyl acrylate and octyl acrylamide has good tack and creates a polymer combination that is synergistic in nature, with reasonable expectation of having polymer adhesive composition made of alkyl acrylate monomer and octyl acrylamide monomer that has good tack and synergist adhesive nature.

Applicants disagree.

As noted above, WO 96/08229 comprises one or more A monomers, one or more optional B monomer and a macromonomer that is a required and necessary component of the disclosed copolymer. The alkyl acrylate and alkyl methacrylate monomers required for use in the practice of applicants' claimed invention can only have up to about 18 carbon atoms in the alkyl group and, as such, are not considered in the art to be macromonomers, as this term is conventionally used in the art and used in the disclosure of the WO 96/08229 patent. The examiners position that the A monomers and the macromers of WO 96/08229 read on applicants' alkyl acrylate and/or alkyl methacrylate monomers is in error. WO 96/08229 does not disclose a polymer comprising A monomer, B monomer and an alkyl methacrylate as the macromonomer.

Use of t-octyl acrylamide as B monomer, together with an A monomer and

macromonomer to prepare the polymer of WO 96/08229 would not result in applicants claim 7 polymer. Applicants' polymer 7 is not prepared using the macromonomers required by WO/ 96/08229. Moreover, there is no motivation provided in Weaver patent to use t-octyl acrylamide as the B monomer component of WO 96/08229 and to delete the macromonomer component of WO 96/08229.

Applicants' claim 7 is not obvious over WO 96/08229 in view of Weaver. Reconsideration and withdrawal of this Section 103 rejection is requested.

7. Claims 18 and 20 are rejected under 35 U.S.C. § 103 (a) as being obvious over WO 96/08229 in view of Müller et al. (U.S. Patent No. 5,458,885).

The examiner acknowledges (office action, paragraph 13) that WO 96/08229 does not teach the acrylate polymer comprising 2-ethyl acrylate and methyl acrylate as required in claims 18 and 19. The Müller patent is cited as teaching transdermal system comprising polymer made of methyl acrylate and 2-ethyl acrylate, where the polymer is suitable to deliver active agents including analgesics. It is the position of the examiner that it would have been obvious to deliver polymer adhesive composition made of alkyl acrylate monomer as disclosed by WO and replace the acrylate monomer with polymer made of methyl acrylate and 2-ethylhexyl acrylate motivated by the teaching of Müller that such a polymer is suitable to deliver drugs, with reasonable expectation of having polymer adhesive composition made of 2-ethylhexyl acrylate, methyl acrylate and acrylamide monomer wherein the polymer provides successful delivery of therapeutic drugs.

Applicants disagree.

As noted above, WO 96/08229 comprises one or more A monomers, one or more optional B monomer and a macromonomer that is a required and necessary component of the disclosed copolymer. The alkyl acrylate and alkyl methacrylate monomers required for use in the practice of the claimed invention can only have up to about 18 carbon atoms in the alkyl group and, as such, are not considered in the art to be macromonomers, as this term is

conventionally used in the art and used in the disclosure of the WO 96/08229 patent. The examiners position that the A monomers and the macromers of WO 96/08229 read on applicants' alkyl acrylate and/or alkyl methacrylate monomers is in error. WO 96/08229 does not disclose a polymer comprising A monomer, B monomer and an alkyl methacrylate as the macromonomer.

Use of B acrylamide monomer, together with an 2-ethylhexyl acrylate and methyl acrylate as A monomer and macromonomer to prepare the polymer of WO 96/08229 would not result in applicants' claim 18 or 20 polymer. Applicants' claimed polymer is not prepared using the macromonomers required by WO/ 96/08229. Moreover, there is no motivation provided in the Müller patent to use 2-ethylhexyl acrylate, methyl acrylate as the A monomer component of WO 96/08229 and to delete the macromonomer component of WO 96/08229.

Applicants' claims 18 and 20 are not obvious over WO 96/08229 in view of Müller. Reconsideration and withdrawal of this Section 103 rejection is requested.

8. Claims 19 and 21 are rejected under 35 U.S.C. § 103 (a) as being obvious over WO 96/08229 in view of Müller et al. (U.S. Patent No. 5,458,885) and further in view of Weaver (U.S. Patent No. 3,491,070).

The examiner (office action, paragraph 14) again urges that it would have been obvious to deliver polymer adhesive composition made of alkyl acrylate monomer and acrylamide as disclosed by WO 96/08229 and replace the alkyl acrylate monomer with methyl acrylate and 2-ethylhexyl acrylate of Müller to produce a polymer adhesive composition made of 2-ethylhexyl acrylate, methyl acrylate and acrylamide monomer. The examiner then urges that it would be obvious to further to replace the acrylamide with the octyl acrylamide of Weaver, motivated by the desire to produce an adhesive having good tack and synergistic adhesive nature.

As noted above, WO 96/08229 comprises one or more A monomers, one or more optional B monomer and a macromonomer that is a required and necessary component of the

disclosed copolymer. The alkyl acrylate and alkyl methacrylate monomers required for use in the practice of the claimed invention can only have up to about 18 carbon atoms in the alkyl group and, as such, are not considered in the art to be macromonomers, as this term is conventionally used in the art and used in the disclosure of the WO 96/08229 patent. The examiners position that the A monomers and the macromers of WO 96/08229 read on applicants' alkyl acrylate and/or alkyl methacrylate monomers is in error. WO 96/08229 does not disclose a polymer comprising A monomer, B monomer and an alkyl methacrylate as the macromonomer.

Use of B t-octyl acrylamide monomer, together with an 2-ethylhexyl acrylate and methyl acrylate as A monomer and macromonomer to prepare the polymer of WO 96/08229 would not result in applicants' claim 19 or 21 polymer. Applicants' claimed polymer is not prepared using the macromonomers required by WO/ 96/08229. Moreover, there is no motivation provided in the either of the Müller patent or Weaver patent, alone or when combined, to use 2-ethylhexyl acrylate, methyl acrylate as the A monomer component of WO 96/08229, t-octyl acrylamide monomer as the B monomer component of WO 96/08229 and to delete the macromonomer component of WO 96/08229. Applicants' claims 19 and 21 are not obvious over WO 96/08229 in view of Müller and further in view of Weaver. Reconsideration and withdrawal of this Section 103 rejection is requested.

Applicants submit that the application is in condition to be allowed. Early and favorable action is requested.

Respectfully submitted,

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